In re application of:	Kapeller-Libermann, Rosana		
Application No.:	10/658,904	Group No.:	1653
Filed:	September 10, 2003	Examiner:	Monshipouri, Maryam
For:	14171 PROTEIN KINASE, A NOVEL HUMAN PROTEIN KINASE AND USES THEREOF		

Practitioner's Docket No. (MPI00-010P1RCP1M) ***PATENT***

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1-571-273-8300

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on June 14, 2006

Paula Swirka

Signature

Paula Swirka

Typed or printed name of person signing Certificate

Submitted herewith:

This Certificate of Transmission under 37 CFR 1.8	1 page
Transmittal of Petition under 37 CFR 1.181 (in duplicate)	4 pages
Petition under 37 CFR 1.181	7 pages
Total	**12 pages** (including this cover sheet)

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Practitioner's Docket No. MPI00-010P1RCP1M *PATENT*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Commissioner for Patents
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TRANSMITTAL OF PETITION UNDER 37 CFR 1.181

1. Transmitted herewith for this application are:
   a. This Transmittal of Petition under 37 CR 1.181 (2 pages, in duplicate);
   b. Petition under 37 CR 1.181 (7 pages);
   c. Certificate of Transmission under 37 CFR 1.8 (1 page).

STATUS

2. Applicant is other than a small entity.

PETITION FOR EXTENSION OF TIME

3. The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136 apply. Applicant believes that an extension of time is not required. However, if an extension of time is required, please consider this a petition therefor.

Fee:	$0
Extension fee due with this request	$0

If an additional extension of time is required, please consider this a petition therefor.

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

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Practitioner's Docket No. MPI00-010P1RCP1M

FEE FOR CLAIMS

4. The fee for claims (37 C.F.R. 1.16(b)-(d)) has been calculated as shown below:

	(Col. 1) Claims Remaining After Amendment		(Col. 2) Highest No. Previously Paid For		(Col. 3) Present Extra	OTHER THAN A SMALL ENTITY Rate		Addit. Fee
Total	20	Minus	20	=	0	$50.00	=	$0.00
Indep.	2	Minus	3	=	0	$200.00	=	$0.00
First Presentation of Multiple Dependent Claims			0			$360.00	=	$0.00
						Total Addit. Fee		$0.00

Total additional fee for claims required $0.00

FEE PAYMENT

5. Charge Account No. 501668 the Petition fee of $130.00 (which includes the $0.00 extension fee and the $0.00 additional fee for claims). A duplicate of this transmittal is attached.

FEE DEFICIENCY

6. If any additional extension and/or fee is required, charge Account No. 501668.
If any additional fee for claims is required, charge Account No. 501668.

7. Correspondence Address
Direct all future correspondence to:

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OR
Intellectual Property Department
MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
Cambridge, MA 02139

June 14, 2006

MILLENNIUM PHARMACEUTICALS, INC.

By _____
Tracy M. Sioussat, Ph.D.
Registration No. 50,609
40 Landsdowne Street
Cambridge, MA 02139
Telephone - 617-374-7679
Facsimile - 617-551-8820

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PETITION UNDER 37 C.F.R. § 1.181

PETITION

1. Pursuant to 37 C.F.R. § 1.181, Applicant petitions for withdrawal of the finality of the rejection made in the Office communication mailed April 14, 2006.

The application as filed contained 20 claims, which were restricted into eight groups in a communication by the Examiner on August 1, 2005. The groups comprised either product or process claims. There was no species election requirement attached to any group. In response, Applicant elected Group II, drawn to "said human kinase and homologs thereof." Since Group IV of claims were drawn to a method of modulating the activity of the kinase, these original claims, which depended from the claims of Group II, were retained as withdrawn, with hope of later rejoinder if the elected claims would be allowed.

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

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TRANSMISSION

☑ transmitted by facsimile to the Patent and Trademark Office (571-273-8300).

Paula Swirka

Signature
Paula Swirka
(type or print name of person certifying)

Date: 14 June 2006

06/15/2006 TL0111 00000020 501668 10658984
01 FC:1464 130.00 DA

During that restriction response, Applicant canceled claims drawn to non-elected and unrelated groups and amended and added claims to be included the elected group II and withdrawn group IV. The first office action on the merits examined only the claims of the elected group. The response to that action was to cancel one dependent claim and add one new claim, both within the elected group. The claim cancellation rendered the claims of the elected group allowable, so the Examiner then turned to the question of rejoinder of the method claims which depended on the product claims.

Applicant is including the listing of claims below and annotating the history of activities around the claims to illustrate petition points 1) and 2) further below:

1. – 4. (Canceled in response to restriction requirement)

5. (elected Group II-Amended in response to restriction requirement, not amended in response to first office action, allowed in 1st office action) An isolated polypeptide selected from the group consisting of:

a) a polypeptide which is encoded by a nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of the nucleotide sequence of SEQ ID NO:1 and SEQ ID NO:3; and

b) ~~a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:2, wherein the fragment comprises at least 300 contiguous amino acids of SEQ ID NO:2 and wherein said at least 300 contiguous amino acids have kinase activity;~~

~~c) an antigenic fragment of SEQ ID NO:2 comprising at least 15 amino acid residues of SEQ ID NO:2; and~~

~~d)~~ a polypeptide ~~having the~~ comprising amino acid ~~sequence~~ residues 1 to 350 of SEQ ID NO:2, wherein the polypeptide has kinase activity.

6. (Original-elected group II, allowed in 1st office action) The polypeptide of claim 5 further comprising heterologous amino acid sequences.

7. – 11. (Canceled in response to restriction requirement)

12. (Original- Group IV claim withdrawn in response to restriction requirement - depends on claim allowed in 1st office action, not rejoined even though it depends on elected claim allowed in 1st office action) A method for identifying a compound which binds to a polypeptide of claim 5 comprising the steps of:

a) contacting a polypeptide, or a cell expressing a polypeptide of claim 5 with a test compound; and

b) determining whether the polypeptide binds to the test compound.

13. (Group IV-Amended in response to restriction requirement, withdrawn, not rejoined) The method of claim 12, wherein the binding of the test compound to the polypeptide is detected by a method selected from the group consisting of:

a) detection of binding by direct detecting of test compound/polypeptide binding;

b) detection of binding using a competition binding assay; ~~and~~

c) detection of binding using an assay for protein kinase-mediated phosphorylation; and

d) detection of binding using a two-hybrid assay.

14. (Canceled in response to restriction requirement)

15. (Original-Group IV claim withdrawn in response to restriction requirement- depends on claim allowed in 1st office action, rejoined and rejected in 2nd office action) A method for identifying a compound which modulates the activity of a polypeptide of claim 5, comprising:

a) contacting a polypeptide of claim 5 with a test compound; and

b) determining the effect of the test compound on the activity of the polypeptide to thereby identify a compound that modulates the activity of the polypeptide.

16. (Original- Group IV claim withdrawn in response to restriction requirement, rejoined and rejected in 2nd office action) The method of claim 15, wherein the activity of the polypeptide is determined in a kinase assay using a 14171 kinase substrate.

17. – 20. (Canceled in response to restriction requirement)

21. (Group II-Added in response to restriction requirement, allowed in 1st office action) The polypeptide of claim 5, wherein the polypeptide comprises SEQ ID NO:2.

22. (Group II-Added in response to restriction requirement, rejected in 1st office action, canceled in response to 1st office action) The polypeptide of claim 6, wherein the heterologous amino acid sequences are selected from the group consisting of glutathione-S-transferase, V5 and histidine residues.

23. (Group IV-Added in response to restriction requirement, withdrawn, not rejoined) The method of claim 12, wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:2.

24. (Group IV-Added in response to restriction requirement, withdrawn, not rejoined) The method of claim 12, wherein the polypeptide is immobilized on a solid surface.

25. (Group IV-Added in response to restriction requirement, withdrawn, not rejoined) The method of claim 12, wherein the test compound is directly or indirectly labeled.

26. (Group IV-Added in response to restriction requirement, withdrawn, rejoined and rejected in 2nd office action) The method of claim 15, wherein the activity of the polypeptide is the ability to bind ATP.

27. (Group IV-Added in response to restriction requirement, withdrawn, allowed, even though dependent on a rejected claim) The method of claim 15, wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:2.

28. (Group IV-Added in response to restriction requirement, withdrawn, rejoined and rejected in 2nd office action) The method of claim 16, wherein the 14171 kinase substrate has a T-P motif.

29. (Group IV-Added in response to restriction requirement, not rejoined, even though it directly depends on a rejoined claim) The method of claim 15, wherein the polypeptide is expressed in a cell and the test compound is contacted with the cell expressing the polypeptide.

30. (Group IV-Added in response to restriction requirement, not rejoined, even though it indirectly depends on a rejoined claim) The method of claim 29, wherein the activity of the polypeptide is selected from the group consisting of:

a) phosphorylation activity; and

b) apoptosis.

31. (Group IV-Added in response to restriction requirement, not rejoined, even though it indirectly depends on a rejoined claim) The method of claim 29, wherein the cell is selected from a group consisting of an epithelial cell and a tumor cell.

32. (Group IV-Added in response to restriction requirement, not rejoined, even though it indirectly depends on a rejoined claim) The method of claim 29, wherein the activity of the polypeptide is determined by determining the activity of a target molecule.

33. (Group IV-Added in response to restriction requirement, not rejoined, even though it indirectly depends on a rejoined claim) The method of claim 32, wherein the activity of the target molecule is selected from the group consisting of:

a) cellular second messenger activity,

b) catalytic/enzymatic activity,

c) reporter gene induction, and

d) cellular growth, differentiation or proliferation.

34. (Group IV-Added in response to restriction requirement, not rejoined, even though it indirectly depends on a rejoined claim) The method of claim 33, wherein the reporter gene induction follows activity selected from the group consisting of nuclear factor-kappaB activity and interleukin-8 activity.

35. (Group II-Added in response to 1st office action, allowed in 2nd office action) An isolated polypeptide consisting of the amino acid sequence of SEQ ID NO:2.

The Examiner's actions at this point have provided me with two reasons to petition in this case.

1) The Examiner decided to rejoin some of the withdrawn claims from the single non-elected

Group IV process invention, but refused to enter all of the withdrawn claims from this group. The non-elected group IV contained three original claims, two of which depended directly from an allowed product claim. One of these was rejoined, the other was not. The claims which were refused rejoinder, including claims that depend on rejoined claims, recited that the kinase product could be in a cell, and the Examiner decided that these method claims were not drawn to an "isolated" polypeptide. However, the restriction requirement did not require the restriction or election between methods of using the polypeptide in solution from using the polypeptide in the cell. The restriction requirement merely grouped the product claims as drawn to the "human kinase" and the process claims as being "drawn to a method of identifying agents which bind or modulate the activity of said kinase." In the absence of a restriction requirement between polypeptides inside or outside the cell, the rejoinder should have applied to all the claims in the withdrawn group. This position is consistent with MPEP §821.04, which states that "all claims to a non-elected process invention must depend from or otherwise require all the limitations of an allowable claim for the claims directed to that process invention to be eligible for rejoinder" (MPEP Rev. 3, August, 2005 page 800-64, reiterated in MPEP §821.04(b) on page 800-68 and page 800-70). If the Examiner considered some of the claims in the withdrawn process group not to be so dependent or contain such limitations, then no rejoinder should have taken place and the restriction requirement should not have been withdrawn. Applicant respectfully requests that either all the claims in group IV be rejoined or the rejoinder be reversed and the restriction requirement be reinstated. If the restriction requirement is reinstated, then Applicant can proceed with canceling all Group IV claims and filing a separate application to claim the process invention of Group IV without threat of double patenting.

2) The Examiner states that Applicant's amendment necessitated making the rejection of the rejoined claims final in this Office action. A) As illustrated in 1) above, the Examiner has somewhat imposed a new restriction requirement, between a polypeptide inside and outside the cell. A restriction requirement should not lead to a final office action. B) Applicant's amendment in response to the first office action on the merits was merely to cancel a dependent claim. The amendment did not change the scope of the claim from which the claims in the non-elected group depend. That claim already was held allowable in the first office action. So even though MPEP §821.04 states that an office action on newly rejoined claims can be made final if rejoinder is after the first office action, the rejoinder occurred relative to claims which were allowable prior to the first office action. Final rejection at this time is only proper where Applicant's amendment or an IDS necessitated the final rejection. The Examiner has not explained how Applicant's amendment necessitated this final rejection. While Applicant could file a request for continued examination to argue the merits of the rejoined claims, Applicant fails to identify a way to achieve examination of non-rejoined process invention Group IV claims dependent from allowed or rejoined claims

within the confines of that process, with their status as withdrawn claims under an implied restriction requirement. Applicant fails to see how canceling and refiling some, but not all Group IV claims would not attract a double patenting rejection, now that the original restriction has been withdrawn. Applicant cannot appeal the rejected Group IV claims, because they have not been twice rejected. Therefore, Applicant finds options unduly limited by this office action and requests that the Final rejection be reconsidered as premature.

In view of these remarks, Applicant respectfully requests reconsideration of the finality of the Office Action mailed on April 14, 2006 in the present application. By way of disclosure, Applicant has presented some of these comments to Debbie Reynolds and the Examiner in telephone conversations on June 13 and Jun 12, 2006, respectively. Since there has been no resolution and this is the two month deadline, this petition is being filed.

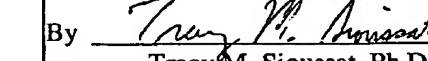
FEE

A petition fee (37 C.F.R. Section 1.17(i)) of $130.00. is to be paid as follows:

☐ Attached is a check in the sum of $130.00..

☑ Charge Deposit Account No. 501668 the sum of $130.00.

A duplicate of this petition is attached.

14 June 2006	MILLENNIUM PHARMACEUTICALS, INC. By  Tracy M. Sioussat, Ph.D. Registration No. 50,609 40 Landsdowne Street Cambridge, MA 02139 Telephone - 617-374-7679 Facsimile - 617-551-8820